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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,251	04/05/2007	Fabrizio Dolfi	29048SUS0X PCT	2049

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
01/20/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/580,251	DOLFI ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-17 and 20-30* is/are pending in the application.

5a) Of the above claim(s) *1-15* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *16,17 and 20-30* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/GB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed October 19, 2011 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 16-17, 20-23, 25, 29 have been amended.

   b. Claim 31 has been cancelled.

2. Claims 1-17, 20-30 are pending in the case.

3. Claims 16-17, 20-30 are present for examination.

4. All grounds not addressed in the action are withdrawn or moot as a result of amendment or argument.

Standing Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 16-17 and 20-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Arkin et al. (WO 02/074290) in view of Bannwarth et al. (Tissue and systemic diffusion of idrocilamide after cutaneous administration).

The translation of Bannwarth is included and all references are to the translation.

The independent claim is directed to a method of treating rosacea with the topical application of a pharmaceutical composition comprising an effective amount of idrocilamide to skin exhibiting signs of inflammatory dermatitis associated with any of the four stages of rosacea to those with fair or sensitive skin (e.g. flushing, papules, pustules, and telangiectasia).

Rejection:

Arkin et al. teaches a method of treating rosacea, a chronic inflammatory disorder, by topically administering a composition comprising a nonsteroidal anti-inflammatory drug. The composition can be a single nonsteroidal anti-inflammatory or a combination of them. The composition can be in conjunction with other conventional rosacea-treating agents preferably with metronidazole. See Examples 2, 4, 5 for the amounts of the nonsteroidal and the additives of the instant claims (e.g. Example 2: NSAID at 0.5%, metronidazole, surfactants-Brij, preservative-parabens, water at about 55% (q.s.=100%-44.9%), meeting the instant claims).The composition can be in various forms including solutions, gels, creams, and emulsions (Page 5).

Arkin teaches that rosacea is common in persons with fair complexions (Page 1), and has various dermatological manifestations (Page 4) encompassing the various stages of rosacea. Presentations include flushing, erythema, telangiectasia, pustules, etc. (all known signs of inflammatory dermatitis of rosacea as stated by the instant specification).

Patients in the different stages of rosacea aged 21-70 were treated with improvement (see Page 4, 9-15). The patient population encompass the various

claimed stages as defined by the instant specification (see Page 2) which addresses that stage 1 is about 20years old, stage 2 is about 30 years old, stage 3 is about 40 years old, and stage 4 is about 50 years old or later fulfilling the instant claims. Additionally as Arkin teaches that the composition is useful for prevention and treatment of the different manifestations of rosacea (Page 1 and 4), it would be *prima facie* obvious to one of skill in the art to use it for the different signs/manifestations for all the stages of rosacea with a reasonable expectation of success as rosacea is a chronic inflammatory dermatitis wit vascular indicators.

Arkin does not expressly teach the inclusion of idrocilamide.

Bannwarth et al. teaches the anti-inflammatory properties of idrocilamide are known and that its topical application was effective. There was a reduction in the pain intensity and concentration of idrocilamide in the area. Bannwarth also teaches that the concentrations are similar when done with a diclofenac gel which is a functionally equivalent nonsteroidal. Bannwarth also teaches that the physicochemical characteristics of idrocilamide as favors its passage through the epidermis (Abstract, Page 2-3, Results Page 4-6, Discussion Page 6-8). It is noted that Applicant cites idrocilamide is known to be an arylpropionic acid NSAID in the instant specification (see Page 3 of instant specification).

It would have been *prima facie* obvious to one of skill in the art at the time of the invention to include idrocilamide in the invention of Arkin, as motivated by Bannwarth, as Bannwarth teaches that idrocilamide is an effective topical NSAID and functionally equivalent to diclofenac; and the general teaching of Arkin is for the topical use of

NSAIDS for rosacea. It would have been *prima facie* obvious to substitute the idrocilamide for the diclofenac in the examples of Arkin as Bannwarth teaches the NSAIDS to be functionally equivalent and topically effective. It is desirable for manufacturers to have functionally equivalent choices to substitute a functionally equivalent NSAID for another when motivated by pricing and availability and topical penetration of the NSAID used to produce the final product, and the physicochemical characteristics of idrocilamide as shown by Bannwarth favors its passage through the epidermis. The skilled artisan would have had a reasonable expectation of successfully treating rosacea by topically applying the composition comprising the NSAID.

Response to Arguments

Applicant's arguments filed 10/19/2011 have been fully considered but they are not persuasive. Applicant's arguments centered on the assertion that idrocilamide is a cinnamide and that Arkin does not teach the cinnamide type structure for the NSAIDS and the descriptive term of NSAID is broad and generic encompassing those not of a steroid base. This is not persuasive as Applicant cites idrocilamide as known to be an arylpropionic acid NSAID in the instant specification (see Page 3 of specification), which is an NSAID class taught by Arkin. If Applicant is asserting that idrocilamide is an NSAID of a cinnamide type (which is not a known NSAID class), and **not** an arylpropionic acid NSAID, *Applicant is arguing the teaching of their own specification and questioning the validity of the instant specification.* It is unclear what Applicant is attempting to address.

Applicant's argument to Bannwarth are centered on the assertion that Bannwarth is not directed to the dermal layer of skin but directed to the topical penetration of the NSAID idrocilamide through skin to muscle, tendon, and joints; and one would not be motivated to look to pain relief of the knee to rosacea. This is fully considered but not persuasive as NSAIDS are widely used topically for various conditions, cuts, burn, joint pain, rosacea, and it is prima facie obvious for one of skill in the art to substitute one known NSAID for another. Bannwarth is merely utilized to demonstrate that the idrocilamide is not only a topically effective anti-inflammatory, but a known functionally equivalent NSAID to diclofenac in the medicinal/pharmaceutical arts. As diclofenac is a taught NSAID in Arkin for the treatment of rosacea; simple substitution of one known NSAID for another is *prima facie* obvious with a reasonable expectation of success particularly as it is known to be useful in the same mode of administration (topical), absent evidence of criticality for the specific NSAID and ranges which has not been presented.

Accordingly, the rejection stands.

Conclusion

6. Claims 16-17, 20-30 are rejected.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:00AM-6:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENIVASAN PADMANABHAN can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/
Examiner, Art Unit 1627
/Zohreh A Fay/
Primary Examiner, Art Unit 1627